



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

June 24, 2016

MEMORANDUM

Subject: Efficacy Review for Mold Killing Primer; EPA File Symbol No. 69587-A; DP
Barcode: D431785

From: Ibrahim Laniyan, Ph.D.
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To: Thomas Luminello / Jacqueline Hardy, RM 34
Regulatory Management Branch II
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Applicant: Rust-Oleum Corporation
11 Hawthorn Parkway,
Vernon Hills, IL 60061

Formulation from the Label:

<u>Active Ingredient</u>	<u>% by wt.</u>
3-Iodo-2-Propynyl Butyl Carbamate	0.15 %
<u>Other Ingredients:</u>	<u>99.85 %</u>
<u>Total</u>	<u>100.00 %</u>

(5000ppm available chlorine)

I. BACKGROUND

The product, Mold Killing Primer (EPA File Symbol 69587-A), is a new product. The applicant requested to register the ready-to-use spray primer paint as a hard, non-porous surfaces mold and mildew fungicide (mold killing property). The registrant submitted, via e-mail, on May 26, 2016, a complimentary package after technical screen rejection. The new package contains "Hard Non-Porous Mildew-Fungistatic" study, instead of, "Hard Non-Porous Mildew-Fungicidal" study, conducted on *Aspergillus niger* (ATCC 6275), at Accuratus, located at 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Evaluation of the product is based on the data submitted as part of the complimentary package (study MRID 499367-01).

This data package identified as D431785, contained a letter from the applicant's representative to the Agency (dated May 26, 2016), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-27 (Formulator's Exemption Statement), EPA Form 8570-35 (Data Matrix), three studies (MRIDs 498126-09, 498126-10, and 499367-01). Statement of No Data Confidentiality Claims for the studies, and the proposed label.

II. USE DIRECTIONS

Check with all local, state and federal regulations prior to using or working with this product. Fix the source of any moisture problems prior to remediation. Do not attempt to salvage damaged or structurally unsound building materials. Consult a qualified professional to perform a thorough inspection and supply work specifications appropriate to the project.

Surface Preparation: *For applications that have existing wet, slimy, heavy soiled, gross filth, overgrowth or loose material on the substrate a pre-cleaning step is required. Physically or mechanically remove gross filth, heavy soil, overgrowth or loose material including dirt, grease and oily films before application and ensure the substrate is free of slime or excessive moisture to ensure long-term adhesion and product performance particularly on exterior surfaces. If mold or mildew needs to be removed prior to application, remove with a mildew remover that is EPA registered and let dry. Wear eye, skin, and NIOSH approved respiratory protection. Patch surface irregularities with appropriate patching compounds.

Application: Mold Killing Primer is a ready to use product. Use at room temperature (70°F) in a well ventilated area –do not use in high humidity conditions. Shake can vigorously until ball inside can rattles. Turn upside down and continue shaking for one minute – shake occasionally during use. If ball does not rattle, do not strike the can. [Contact Rust-Oleum.] Spray 10-12" from object with short dusting strokes. If valve clogs, twist and pull off spray tip and rinse it in a solvent such as mineral spirits. Do not stick pin or other object into the stem.

Mold, Mildew, Fungi, and Odor Causing Bacteria Control: Mold Killing Primer will kill all existing mold, mildew and fungal organisms. Apply Mold Killing Primer generously and uniformly, ensuring that the surface is completely coated. Allow to dry.

Coverage: Approximately [8, 12, 14, 15, 16, 18, 20] sq. ft. per can.

Drytime: Dries in minutes; topcoat in 30 minutes with latex or oil-base paints. [For optimal protection, apply a topcoat that prevents mold & mildew on the paint film within 72 hours of application.] Full adhesion and hardness develops in 7 days. [For best results allow primer to cure

overnight when applying strong solvent-base topcoats.]

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Hard Surface Mildew Fungistatic Test: This method is intended to be used in supporting fungistatic claims for the control, treatment, or prevention of fungi and subsequent mildew growth on hard surfaces. Use of this test method in no way supports claims for use of a product as a fungicide. The test is to be conducted on 10 glazed ceramic tiles for each of two product lots against *Aspergillus niger* (ATCC 6275). Ten untreated glazed tiles are to be used as the control, on which greater than 50% of each tile is to be covered with fungal growth after 7 days for the test to be considered valid. Growth observations are to be made visually after 7 days intervals of incubation. If no visible growth is evident at the end of the test period, examination at a 15X magnification must take place. A product dosage is considered acceptable when all ten treated replicates are free of fungal growth. The acceptance criterion requires that all ten treated replicates per batch must be free of fungal growth. The directions for use must specify retreatment every 7, 14, or 21 days, as necessary depending on the length of time that all of the test carriers remain free of mildew growth. Labeling of products which do not permit growth after four weeks incubation must specify a retreatment schedule, such as "repeat as necessary when new growth appears", and should indicate that treatments should be effective for at least 28 days.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 499367-01 "EPA Hard Surface Mildew-Fungistatic Test" for Mold Killing Primer Aerosol. Test microorganism: *Aspergillus niger* (ATCC 6275); by Jamie Herzan. Study conducted at ACCURATUS. Study completion date – May 13, 2016. Project number: A20729.

Percentages of 3-Iodo-2-propynyl-butylcarbamate (IPBC) in tested lots according to the submitted CoA are: lot 600-075, 0.1354% and lot 600-077, 0.1301%

This study was conducted against *Aspergillus niger* (ATCC 6275). Two lots (600-075 and 600-077) of the product, Mold Killing Primer, at the LCL, and one Aerosol Paint Control - Blank Book 600-075, were tested according to Accuratus Protocol No. RU001040416.MSTAT (copy not provided). The product was received ready-to-use, aerosol spray. Fetal bovine serum (FBS) was added to the inocula at a concentration of 5%, to simulate an organic soil load. Ten (10) glazed ceramic tiles carriers per product lot were sprayed with the test substance at a distance of 8 to 12 inches using one spray or until thoroughly wet (actual spray time used 3 seconds). For the test substance control, the surfaces of 3 carriers were sprayed with the test substance control at a distance of 8 to 12 inches using one spray or until thoroughly wet (actual spray time used 3 seconds). The treated carriers were placed in a vertical or near vertical position to permit excess liquid to drain. The carriers were dried in Petri dishes at 35-37°C for 30 minutes with the lids ajar. Carriers were contaminated using an atomizer containing *Aspergillus niger* conidia-Czapek suspension. Approximately 3 sprays were used to apply the test organism. The atomizer was periodically mixed to agitate the culture during inoculation. Carriers contained in Petri dishes were returned to a 35-37°C incubator and dried with the lids slightly ajar for 30 minutes until visibly dry. Each carrier (sprayed side up) was placed onto an individual water agar plate. All plates were incubated for 7 days at 25-30°C in a minimum of 95% relative humidity. All test and control carriers were examined after 7 days of incubation. The absence of fungal growth on all carriers is the criterion for determining the effectiveness of the test product. No visual growth was evident at the

end of the 7 days on test carriers therefore a magnified examination was performed. To be considered a valid test, each untreated control carrier must be at least 50% covered with fungal growth after the 7 days. Controls included purity and sterility.

VI. RESULTS

MRID 499367-01	Days	Visual and Magnified Evaluation of Carriers (% Coverage)									
		1	2	3	4	5	6	7	8	9	10
Untreated Control	7	60	60	70	75	75	75	65	60	80	65
Cont. lot 600-075	7	70	40	65	-	-	-	-	-	-	-
Lot 600-075	7	0	0	0	0	0	0	0	0	0	0
Lot 600-077	7	0	0	0	0	0	0	0	0	0	0

VI. CONCLUSION

1. The submitted efficacy data (MRID 499367-01) **support** the use of the product, Mold Killing Primer, as a hard non-porous surface mold and mildew-fungistatic for 7 days when used as an aerosol spray on hard, non-porous surfaces in the presence of a 5% organic soil load (fetal bovine serum) at room temperature.

Fungistatic test is a 7-day interval reading test (7, 14, 21, and 28). Submitted test results did not show static activities past 7 days. Technically, reapplication must extend static activity for another week unless killing was demonstrated by using a Non-Static (Mildew-fungicidal) Test containing Neutralization Confirmation Step.

VII. LABEL

1. The proposed label claims that the product, Mold Killing Primer (File Symbol 69587-A), is an effective mold and mildew fungicidal coating primer, **are not acceptable** as they are not supported by the applicant data.

The product demonstrated mildew-fungistatic ability for 7 days. Claims are for the control, treatment, or prevention of mold/mildew and subsequent mold/mildew growth on hard non porous surfaces. The direction for use must specify retreatment every 7days as necessary (**not practical or unrealistic**).

2. The applicant must make the following changes to the proposed label, as appropriate:

- The product name "Mold Killing Primer" is misleading and must be changed as of product supporting data submitted to the Agency is for growth control. Killing of mold was not demonstrated to the Agency. If registrant decided to keep the product name, acceptable data generated using "Glass Slide (or comparable surface) Mildew Fungicidal Test Method" must be submitted to Agency.
- Replace all fungicidal claims mold killing claims with "7-day (one week) Mold and Mildew-fungistatic claims" or "one week mold/mildew control, treatment, or prevention claims."
- Remove all bacteria killing claims.